Attorney's Docket No.: 10848-018001 / 412023GA-go

Applicant: Wolf Bertling Serial No.: 10/049,574 Filed: July 16, 2002

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Amendments to the Claims:

Please amend claims 1, 5, and 11 as follows. Please cancel claim 6 without prejudice to continued prosecution. The claims and their status are shown below.

- 1. (Currently amended) A method for indirectly determining blood clotting status <u>INR</u> (<u>International Normalized Ratio</u>) having the following steps:
- a) providing a sample of body fluid which contains a protein which can be modified by a vitamin K-dependent γ-carboxylase, wherein the body fluid is plasma, blood, saliva, or urine,
- b) measuring at least two concentrations selected from a group consisting of a first concentration (C1) of carboxylated protein, a second concentration (C2) of decarboxylated protein and a total concentration (C3) of carboxylated and decarboxylated protein, where the first concentration (C1) is measured using a first antibody (A1), the second concentration is measured using a second antibody (A2) and the third concentration (C3) is measured using a third antibody (A3),
- c) forming a first ratio (R1) from the first (C1) and second concentration (C2) or forming a second ratio (R2) from the third (C3) and first concentration (C1) or forming a third ratio (R3) from the third (C3) and second concentration (C2),

where a concentration (C1, C2, C3) which is necessary for forming the first (R1), second (R2) or third (R3) ratio and is not measured in step b) is calculated in accordance with the following relation:

$$C3 - C2 = C1$$

and

- d) correlating the first, second or third ratio (R1, R2, R3) with the blood clotting status.
- 2. (Previously presented) The method as claimed in claim 1, where in step b) additionally at least a first competitor (K1) is used to measure the first concentration (C1), a second competitor (K2) is used to measure the second concentration (C2) or a third competitor (K3) is used to measure the third concentration (C3).

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3. (Previously presented) The method as claimed in claim 2, where at least one of the antibodies (A1, A2, A3) or at least one of the competitors (K1, K2, K3) is conjugated to a labeling substance.

- 4. (Previously presented) The method as claimed in claim 2, where in place of measuring the at least two concentrations as in step b), a combined signal correlating therewith is generated and measured by using two antibodies selected from a group consisting of the first (A1), the second (A2) and the third antibody (A3) and, where appropriate, at least one of the competitors (K1, K2, K3), and is directly correlated with the blood clotting status.
- 5. (Currently amended) The method as claimed in claim 4, where the combined signal is a combined color generated in particular by fluorescent dyes, a fluorescent signal elicited by the Förster effect or a reduction caused by the quencher in a fluorescent signal.
 - 6. (Canceled)
- 7. (Previously presented) The method as claimed in claim 1, where the measurement of the first (C1), second (C2) and/or third concentration (C3) or of the combined signal takes place by an immunological method.
- 8. (Previously presented) The method as claimed in claim 7, where in the immunological method, at least one of the antibodies (A1, A2, A3) is immobilized on a support.
- 9. (Previously presented) The method as claimed in claim 1, where the first (C1), second (C2) and/or third concentration (C3) and/or the combined signal is measured by means of a color reaction or fluorescence detection.
- 10. (Previously presented) The method as claimed in claim 1, where the protein which can be modified by a vitamin K-dependent γ-carboxylase is prothrombin, factor VII, factor IX, factor X, nephrocalcin or osteocalcin.
- 11. (Currently amended) A kit for carrying out the method as claimed in claim 1, having a first antibody (A1) for immunological determination of a first concentration (C1) of the carboxylated form of the protein and having a second antibody (A2) for immunological determination of a second concentration (C2) of the decarboxylated form of the protein, characterized in that the first (A1) and second antibodies (A2) is in each case conjugated to a labeling substance, where the labeling substances are selected so that they are able together to generate a combined signal, wherein said combined signal represents C1 + C2.

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12. (Previously presented) A kit as claimed in claim 11, where the labeling substance is an enzyme, a fluorescent dye or a quencher.

- 13. (Previously presented) A kit as claimed in claim 11, where the combined signal is a combined color, a fluorescent signal elicited by the Förster effect or a reduction caused by a quencher in a fluorescent signal.
- 14. (Previously presented) A kit as claimed in claim 11, where the protein is prothrombin, factor VII, factor IX, factor X, nephrocalcin or osteocalcin.
 - 15-23. (Canceled)
- 24. (Previously presented) The method of claim 3, wherein the labeling substance is selected from the group consisting of an enzyme, a fluorescent dye, a quencher, a gold particle, a latex particle, biotin, streptavidin, and avidin.
- 25. (Previously presented) The method of claim 8, wherein the support is selected from the group consisting of a plastic, a magnetic particle, a latex particle, a gold particle, a test strip, and a membrane.